



SAMHSA-HRSA Center for Integrated Health Solutions

Reversing Early Mortality Due To Obesity and Cardiovascular Risk Factors In Mental Illness: *What Works In Changing Health Behaviors?*

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Disclosures

Grant Funding:

- NIMH
- CDC
- HRSA
- Endowment for Health
- CMS

Consultant:

- Substance Abuse and Mental Health Administration

Overview

- Obesity risk factors and cardiovascular mortality
- Findings from the research literature physical activity and weight loss interventions for persons with mental illness
- What is more (and less) likely to work
- Recommendations

Polling Question: In your practice setting, does your program provide:

- | | | |
|--|-----|----|
| 1. Education in Nutrition and Fitness? | Yes | No |
| 2. Group Exercise Activities? | Yes | No |
| 3. Individual Fitness Coaching? | Yes | No |
| 4. Individual Nutrition Evaluation | Yes | No |
| and Dietary Planning? | Yes | No |
| 5. Both Nutrition Planning and | Yes | No |
| Fitness Coaching? | | |



How we got here.....

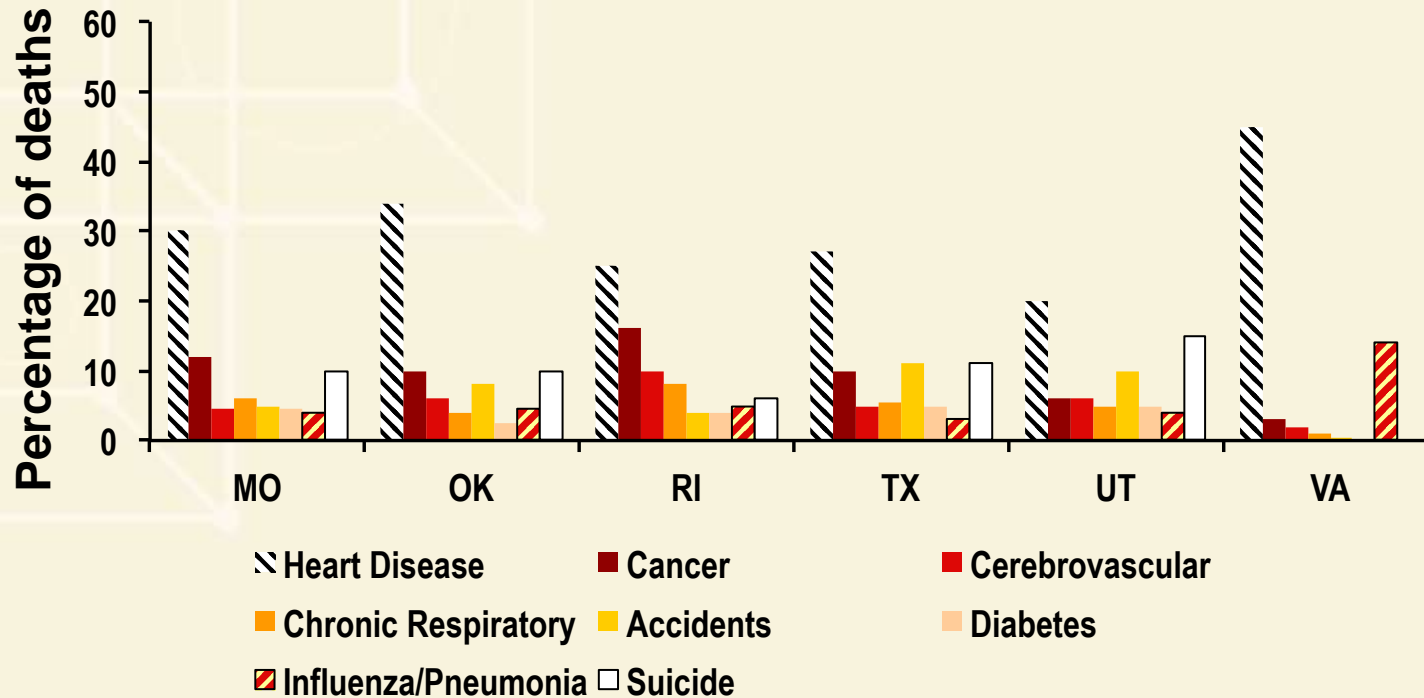
“Epidemic” of Early Mortality: Mean Years of Potential Life Lost

Year	AZ	MO	OK	RI	TX	UT
1997		26.3	25.1		28.5	
1998		27.3	25.1		28.8	29.3
1999	32.2	26.8	26.3		29.3	26.9
2000	31.8	27.9		24.9		

Compared with the general population, persons with major mental illness lose 25-30 years of normal life span

Colton CW, Manderscheid RW. Prev Chronic Dis [serial online] 2006 Apr [date cited]. Available at:
URL:http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm

Cardiovascular Disease: Primary Cause of Death in Persons with Mental Illness*



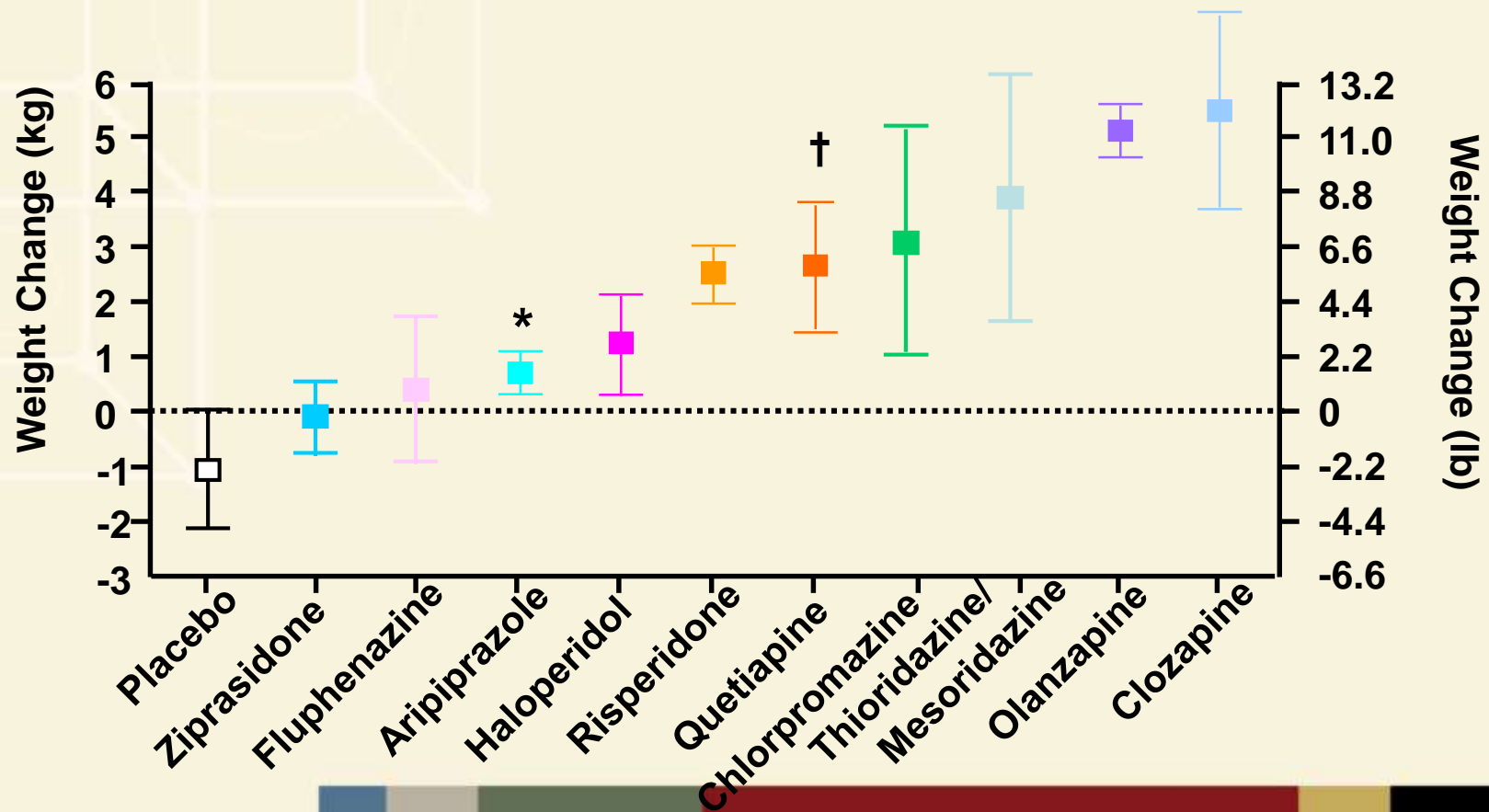
*Average data from 1996-2000.

Colton CW, Manderscheid RW. Prev Chronic Dis [serial online] 2006 Apr [date cited].

Available at URL: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm

Mean Change in Weight With Antipsychotics

Estimated Weight Change at 10 Weeks on “Standard” Dose



*4–6 week pooled data (Marder SR et al. *Schizophr Res.* 2003;1;61:123-36; †6-week data adapted from Allison DB, Mentore JL, Heo M, et al. *Am J Psychiatry.* 1999;156:1686-1696; Jones AM et al. *ACNP*; 1999.

Polling Question: Determinants of Health

How Much is Due to Health Care?

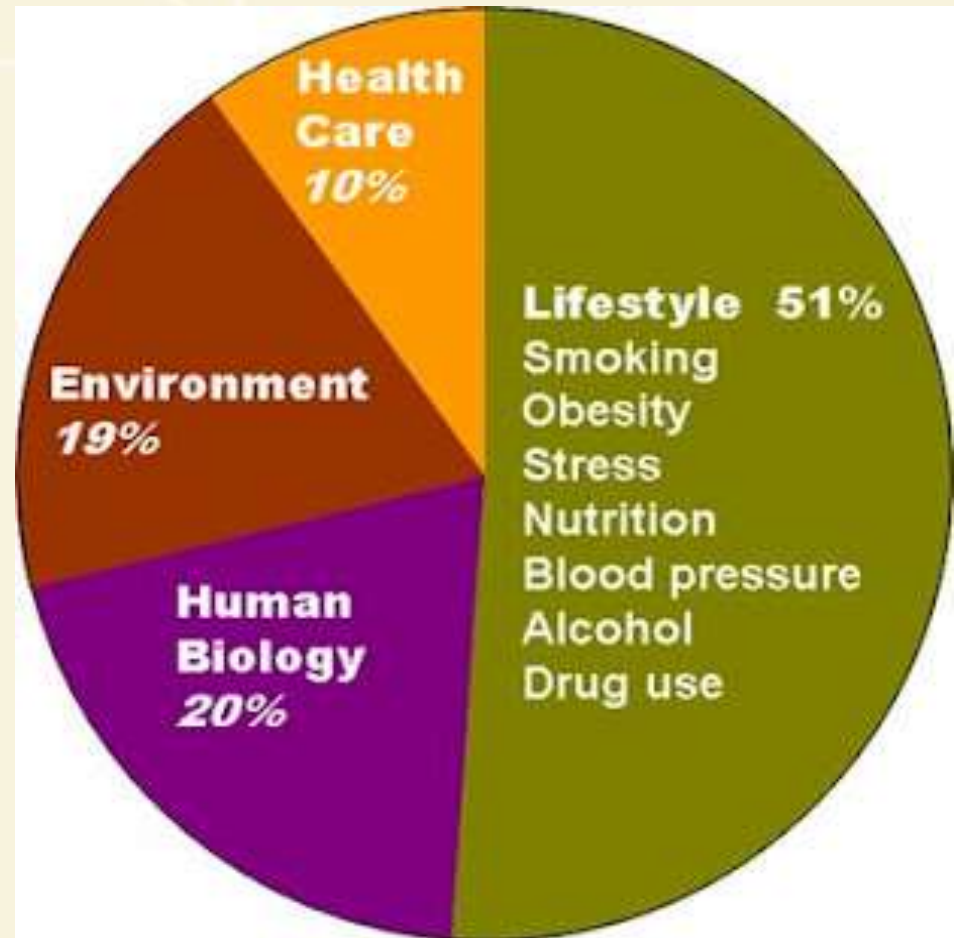
How Much is Due to Health Behaviors?

(with the rest due to genetics and environment)

- a) Health Care 40% / Health Behaviors 20%
- b) Health Care 33% / Health Behaviors 33%
- c) Health Care 10% / Health Behaviors 50%
- d) Health Care 25% / Health Behaviors 33%
- e) Health Care 50% / Health Behaviors 25%

Determinants Of Health (World Health Organization)

Lifestyle **5X**
Health Care



Polling Question:

Factors Affecting Premature Mortality

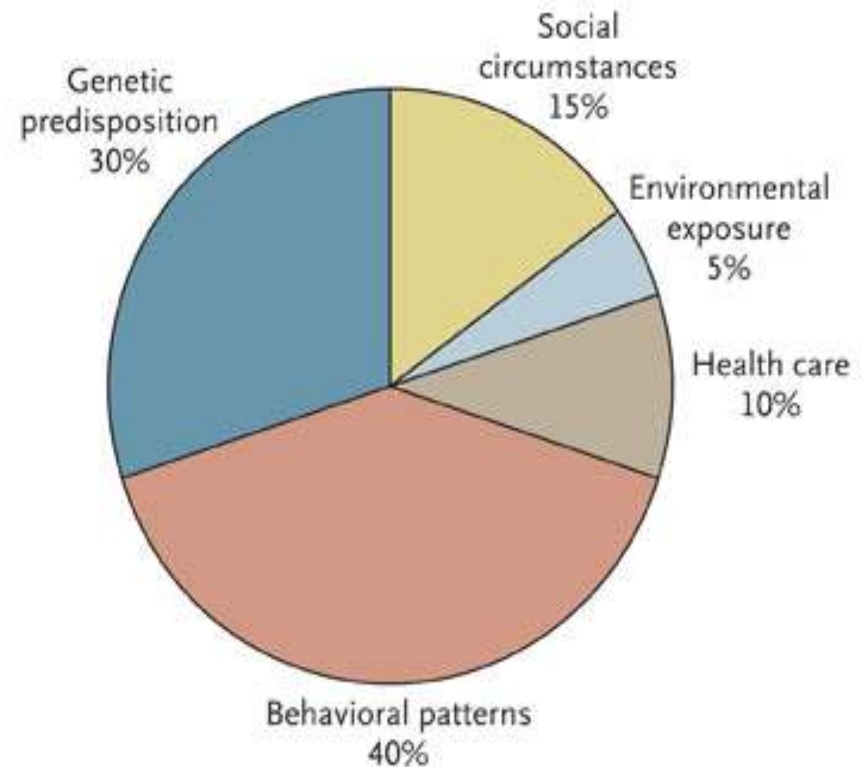
How Much is Associated With
Health Behaviors vs. Health Care

- a) Health Behaviors 2X Health Care
- b) Health Behaviors 3X Health Care
- c) Health Behaviors 4X Health Care
- d) Health Behaviors 5X Health Care

Factors Affecting Premature Death in the Population:

Health Behaviors
4X Health Care

Proportional Contribution to Premature Death



Source: N Engl J Med. 2007 Sep 20;357(12):1221-31

Selected Risk Factors Attributable to Premature Mortality Worldwide

Attributable Risk Factor	Percentage of Annual Deaths
High blood pressure	12.8%
Tobacco use	8.7%
High blood glucose	5.8%
Physical inactivity	5.5%
Overweight & obesity	4.8%
High cholesterol	4.5%
<i>Total</i>	<i>42.1%</i>



Source: World Health Organization (2009)

Cardiovascular Disease Risk Factors

Modifiable Risk Factors	Estimated Prevalence and Relative Risk (RR)	
	Schizophrenia	Bipolar Disorder
Obesity	45–55%, 1.5-2X RR ¹	26% ⁵
Smoking	50–80%, 2-3X RR ²	55% ⁶
Diabetes	10–14%, 2X RR ³	10% ⁷
Hypertension	≥18% ⁴	15% ⁵
Dyslipidemia	Up to 5X RR ⁸	

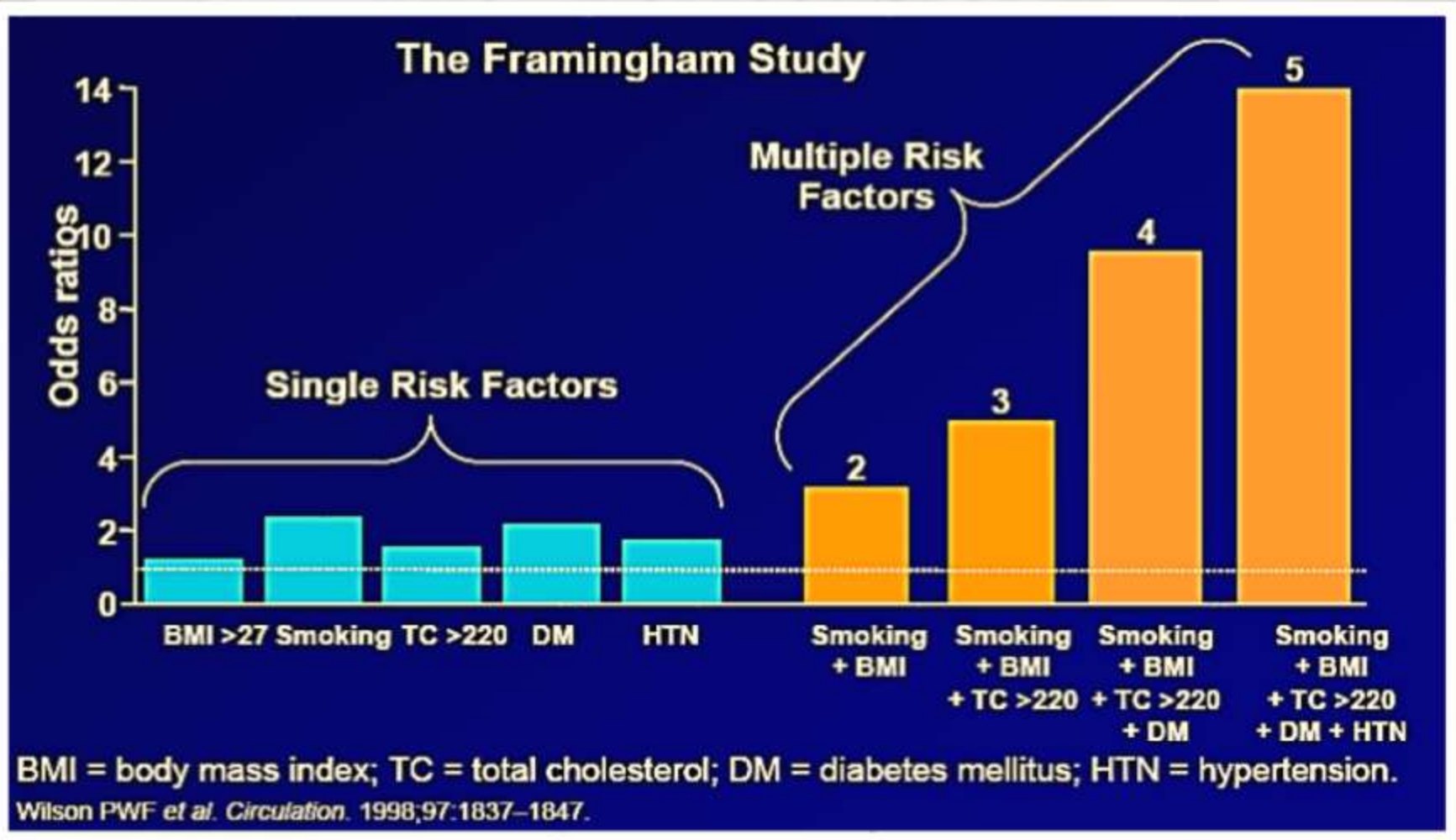
1. Davidson S, et al. *Aust N Z J Psychiatry*. 2001;35:196-202. 2. Allison DB, et al. *J Clin Psychiatry*. 1999; 60:215-220.
3. Dixon L, et al. *J Nerv Ment Dis*. 1999;187:496-502. 4. Herran A, et al. *Schizophr Res*. 2000;41:373-381.
5. MeElroy SL, et al. *J Clin Psychiatry*. 2002;63:207-213. 6. Uçok A, et al. *Psychiatry Clin Neurosci*. 2004;58:434-437.
7. Cassidy F, et al. *Am J Psychiatry*. 1999;156:1417-1420. 8. Allebeck. *Schizophr Bull*. 1999;15(1)81-89.

Obesity Risk Factors for Persons with Serious Mental Illness

- Obesity: > 42% (vs. 28% gen pop)
- 3-6X greater risk of metabolic syndrome
- Regular Moderate Exercise < 20%
- Compared to the general population:
 - Fewer fruits and vegetables
 - More calories and saturated fats

Cardiovascular Risk Factors

The “Perfect Storm”



The Good News: Reducing Risks of Cardiovascular Disease

Maintenance of ideal body weight (BMI = 18.5-25)

- 35%-55% ↓ in CVD

Maintenance of active lifestyle (~30-min walk daily)

- 35%-55% ↓ in CVD

Cigarette smoking cessation

- ~ 50% ↓ in CVD

Hennekens CH. *Circulation* 1998;97:1095-1102.

Rich-Edwards JW, et al. *N Engl J Med* 1995;332:1758-1766.

Bassuk SS, Manson JE. *J Appl Physiol* 2005;99:1193-1204.

What is the Effectiveness of Health Promotion Programs for Persons with Serious Mental Illness?

What works more?

What works less?



Polling Question: Characteristics of Effective Health Promotion Interventions for Persons with SMI

What works best?

- a) Intensive Health Promotion Education
- b) Intensive 12 week Exercise Programs
- c) Diet
- d) Combined Exercise and Nutrition Programs
- e) Frequent weighing

Characteristics of Studies with Statistically Significant Results

- Duration \geq 24 weeks
- BOTH Education and Activity
- BOTH Diet & Exercise
- Manualized & intensive programs
- Ongoing Measurement and Feedback of Success (e.g., Monitoring Physical Activity, Nutrition Change, Weekly Weights)

Polling Question :

What does it mean if a health promotion program reports statistically significant ($p < .05$) results?

- a) It will reduce the risk of chronic illness such as heart disease or diabetes
- b) It should be adopted as an evidence-based practice
- c) The result found is unlikely to be due to chance
- d) It is a large enough effect to make a difference with respect to health outcomes

Limitations.....

- To date, **clinically significant** mean weight loss (>5%) has been elusive.....
- Studies generally limited to
- brief duration (3-6 months)
- Small study samples
- Few well-designed RCTs



Results

- 12 RCTs: Median weight loss: 5.5 lbs
- 18 Controlled Comparison Studies:
 - Over half (55%) statistically significant weight loss
 - BUT NONE of the community-based trials achieved a mean (average) clinically significant (5%) weight loss
 - Community-based health promotion interventions achieving clinically significant reduction in risk:
 - 38% of participants > 5% weight loss (Daumit 2013)
 - 49% of participants either > 5% weight loss or clinically significant improvement in fitness (Bartels 2013)

Health Promotion Implementation Resource Guide: Implementation Ready Health Promotion Programs

Intervention	Author	Design	Duration	Report Clinical Signif	Results
Behavioral Therapy	Brar (2005)	RCT	14 weeks	✓	27% with $\geq 5\%$ wt loss
DART	McKibbin (2006)	RCT	24 weeks		5 lbs wt loss
SIMPLE	Jean-Baptiste (2007)	RCT	16 weeks	✓	6.4 lbs wt loss
Lifestyle Intervention	Wu et al (2008)	RCT	12 weeks		3-10 lbs wt loss
RENEW	Brown (2011)	RCT	6 months		4.4 lbs wt loss
HEALTH	Mangurian (2012)	Comp	14 weeks	✓	24% with $\geq 5\%$ wt loss
Eli Lilly Solutions For Wellness	Industry Supported	5 Pre-Post 3 RCTs	12 weeks		0.1-8.7 lbs wt loss
Behavioral Wt-Loss Intervention	Daumit (2013)	RCT	18 months	✓	37.8 $\geq 5\%$ wt loss vs. 22.7% in control group
In SHAPE	Bartels (2013)	RCT	12 months	✓	49% $\geq 5\%$ wt loss <i>or</i> clin significant fitness

¹Recovery Through Nutrition and Exercise for Wt Loss, ²Simplified Intervention to Modify Physical Activity, ³Lifestyle, Eating Behavior, Healthy Eating and Activity in Latinos Treated in the Heights

Behavioral Weight-Loss Intervention

Daumit et al. NEJM 2013:

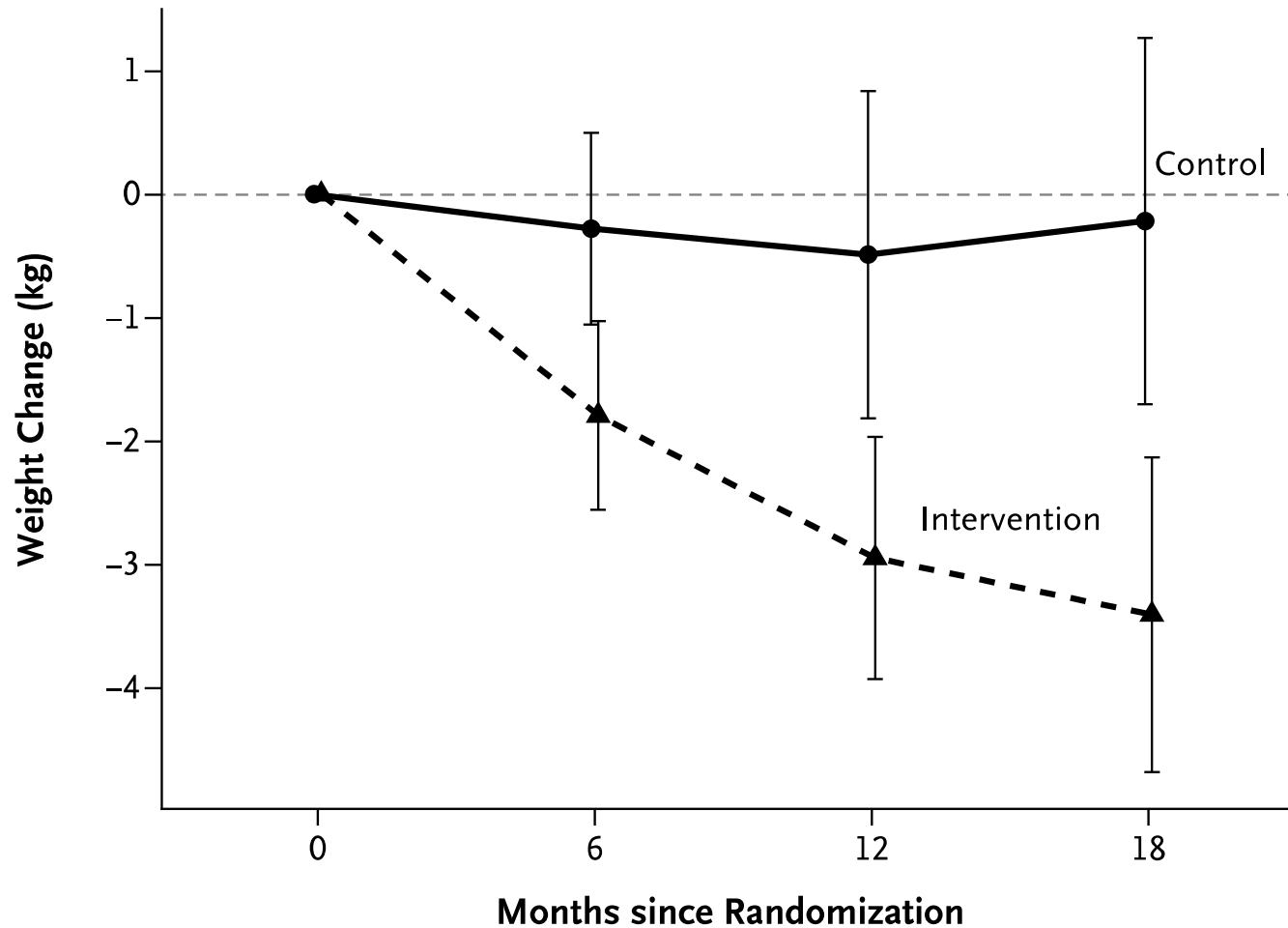
18-month intervention with group & individual weight-management sessions and group exercise sessions

Control – standard nutrition and physical-activity information at baseline

N=291 participants with SMI (58.1% schizophrenia or schizoaffective)

At 18 months -3.2 kg in intervention compared to control (p=0.002)

37.8% in intervention group lost $\geq 5\%$ body weight compared to 22.7% in control group (p=0.009)



IN SHAPE Health Promotion Program

- Individualized fitness and healthy lifestyle assessment
- Individual Meetings with a “Health Mentor”
- Membership Vouchers to Local Fitness Centers
- Group Health Education/Motivational “Celebrations”
- Nurse Evaluation and Consultation

Promoting Health and Functioning in Persons with SMI: CDC - R01 DD000140 (PI: Bartels)

Health Promotion and Fitness for Younger and Older Adults With SMI: R01 MH078052-01 (PI: Bartels)

The In SHAPE Health Promotion Intervention

- Participants spend time each week with personal mentors working out, taking walks, in classes or working on nutrition plans.
- Mentors help participants to track their progress, set goals, and stay motivated.

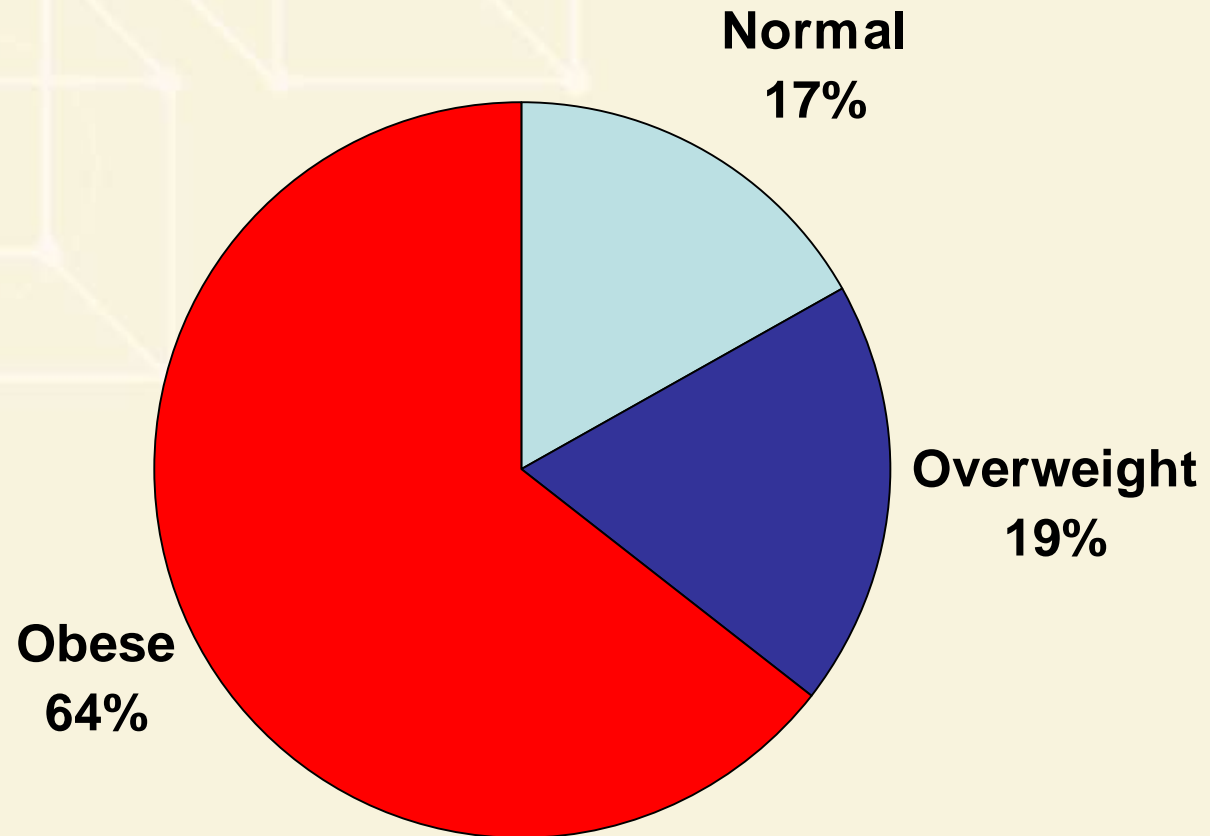




The In SHAPE Health Mentor Program



Body Mass Index

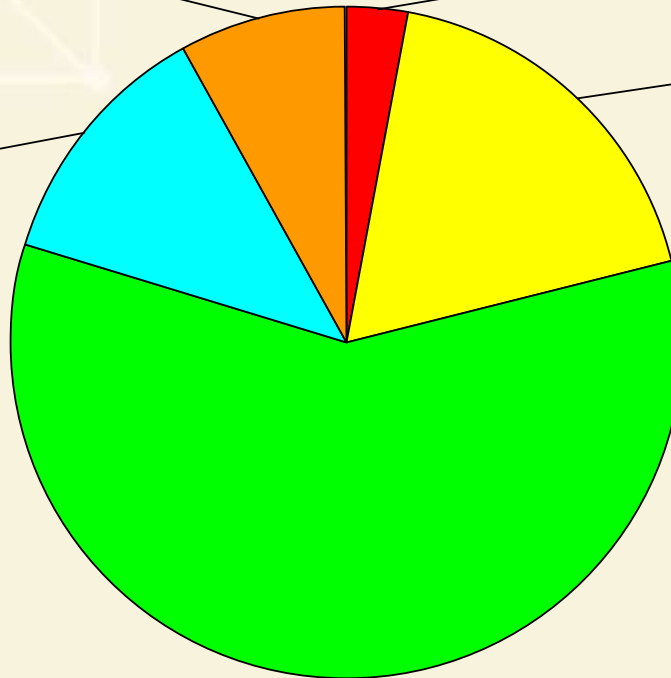


Average weight = 204 pounds

Do you Exercise Regularly?

**Exercising > 6
months**
8%

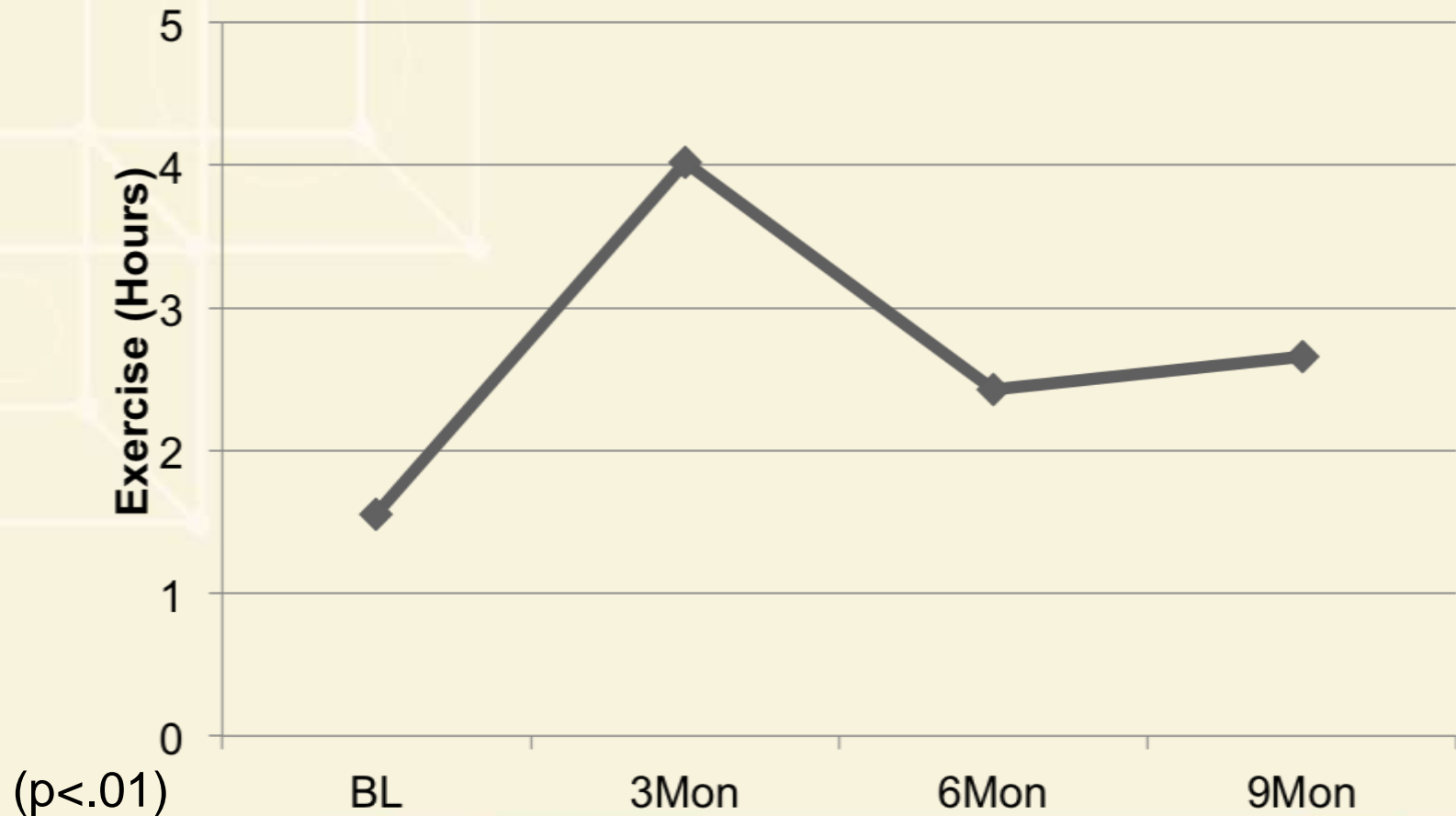
**Exercising < 6
months**
12%



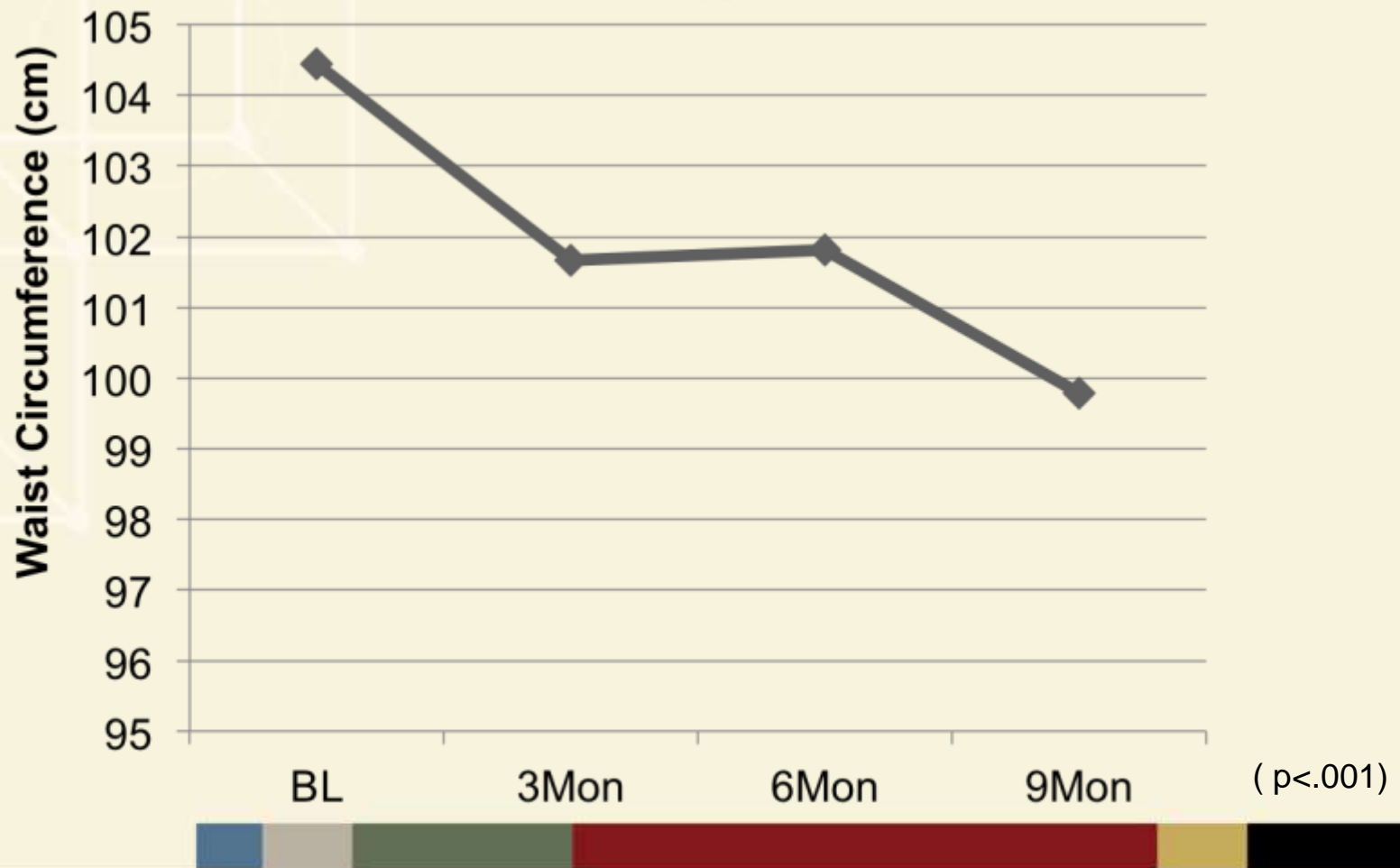
**Pre-
contemplation**
3%
**Thinking about
it**
18%

**Planning to do
it**
59%

In SHAPE Pilot Study: Hours of Exercise (n=76)



In SHAPE Pilot Study Waist Circumference (n=76)



Results of a Randomized Trial for In SHAPE

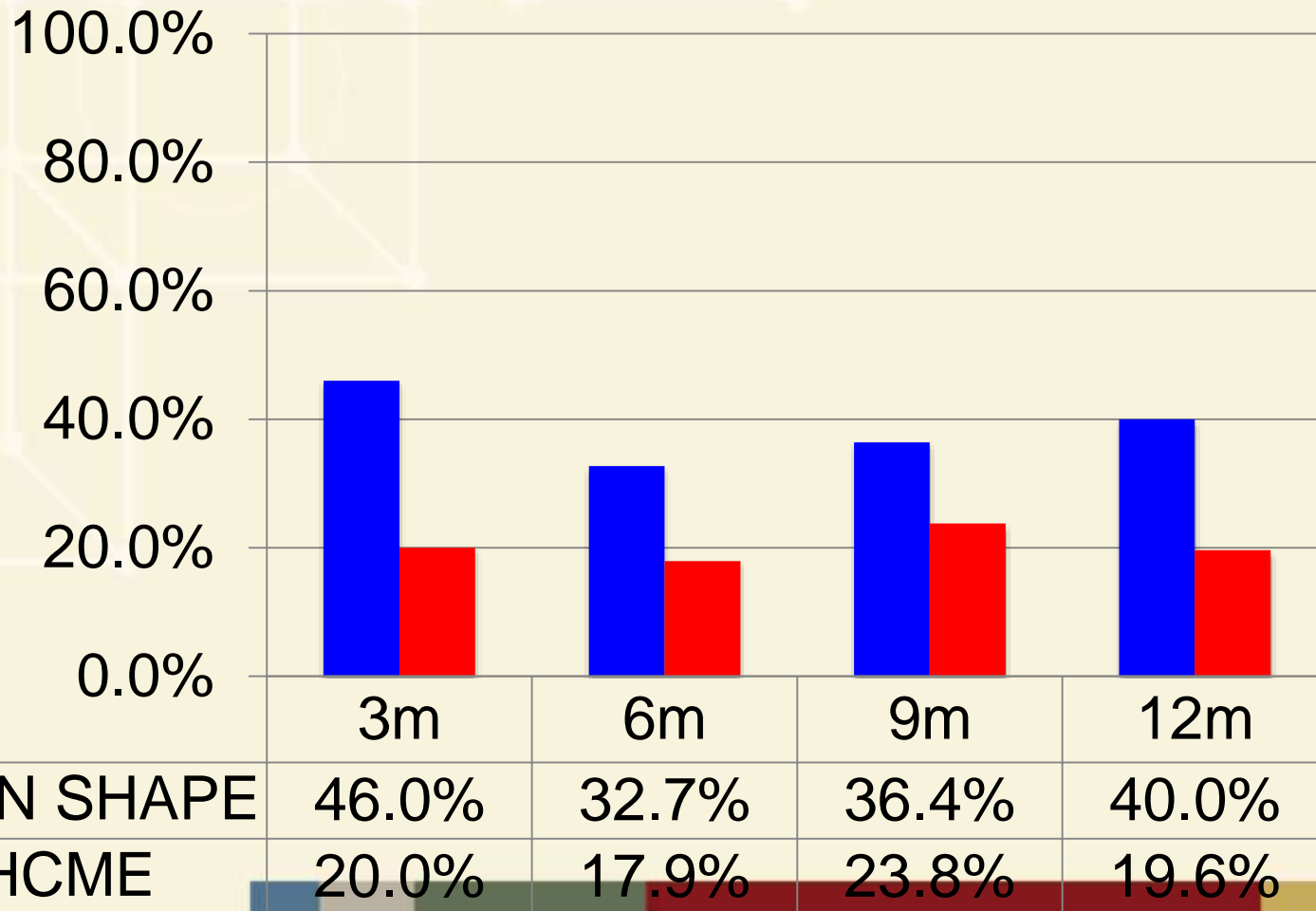
Sample: n=133; mean baseline wt = 231.8 lbs, mean BMI 37.6
31% schizophrenia spectrum, 35% bipolar disorder, 34% depression.
In SHAPE vs. Fitness Club Membership and Education

In SHAPE + Health Club Membership vs. Health Club Membership alone- Greater:

- **40% vs. 19%** Achieved clinically significant improved fitness
- **24.4% vs. 8.7%** achieved BOTH clinically significant improved fitness AND clinically significant weight loss
- Almost ½ (**48.9%**) Either achieved clinically significant weight loss Or improved fitness

Bartels et al., Psychiatric Services August Issue 2013

**% Clinically Significant Improved Fitness:
> 50 Meter Increase on 6 Min Walk Test**



Polling Question: “Fitness vs. Fatness”

TRUE or FALSE:

Achieving clinically significant improvement in fitness for an overweight person will result in a substantial reduction in cardiovascular risk, even if no weight loss is achieved.

Fitness vs. “Fatness”

What if Weight Loss is Not Achieved?

Improved cardiorespiratory fitness vs. weight loss in cardiovascular and all-cause mortality: strongly associated with reduced risk regardless of weight loss.

Systematic review : all-cause mortality: ≥ 150 minutes moderate to vigorous physical activity/week = 86% reduced all cause mortality.

Mean increase in 6MWT 80 meters, clinically significant reduction in risk for cardiovascular and other chronic health conditions.

Lee et al. Circulation 124:2483-2490, 2011, Samitz et al., International Journal of Epidemiology 40:1382-1400, 2011; Larsson & Reynisdottir. Physiotherapy Research International 13:84-93, 2008; Rasekaba et al. Internal Medicine Journal 39:495-501, 2009; Wise & Brown. Journal of Chronic Obstructive Pulmonary Disease 2:125-129, 2005

In SHAPE: Estimate of Potential Cost-Offset

Per-person annual cost of In SHAPE; \$1450 (rural) to \$1692 (urban).

Annual health care costs for diabetes in schizophrenia 92012 adjusted dollars= \$3,015).

5-year cost of diabetes in schizophrenia = \$15,075.

If In SHAPE prevents diabetes in 10% of participants, savings achieved over 5 years would offset the costs of providing In SHAPE as a 12-month intervention.

Leslie & Rosenheck. Psychiatric Services 56:803-809, 2005

What works?

Summary Recommendations

Polling Question:

The Research on Health Promotion for Persons with Mental Illness Shows that Programs Are Most Likely to Be Effective If They Are:

- a) Longer duration (at least 6 months)
- b) Combine education and coached activity
- c) Include both nutrition and physical exercise
- d) Are evidence-based (proven effective by RCTs)
- e) All of the above

Recommendation:

1. **Most** likely to be effective:



- Longer duration (at least 6 months)
- Combine education and coached activity
- Include both nutrition and physical exercise
- Are evidence-based (proven effective by RCTs)

Recommendation:

2. Less likely to be successful:



- Briefer duration interventions
- General wellness or health promotion education-only programs
- Non-intensive, unstructured, or non-manualized interventions
- Programs limited to nutrition only or exercise only (as opposed to combined nutrition and exercise).

Recommendation:

3. *If weight loss is a primary goal:*

- The nutritional component is critical and is more likely to be successful if it incorporates active weight management
- Monitoring weight, changing diet and keeping track



Recommendation:

4. *If physical fitness is a primary goal:*

➤ (+) Activity based programs that provide active and intensive exercise and monitoring of physical activity

➤ (-) Programs solely providing education, encouragement, or support for engaging in physical activity.



Recommendation:

5. Integration of Evidence-based Health Promotion as a Core Service:



➤ Evidence-based health promotion consisting of combined physical fitness and nutrition programs should be an integrated component of mental health services seeking to provide overall wellness and recovery for persons with SMI.

Recommendation:

6. *Pursuing Weight loss vs. Fitness*



➤ Aggressively pursue dietary reform and weight management but also support the value of physical activity in achieving fitness independent of obesity.

Recommendation:

7. Measuring Outcomes and Fidelity



➤ Physical fitness and weight outcomes and evidence-based program fidelity should be objectively and reliably measured as a core indicator of quality mental health services.

Recommendation:

8. *Selecting a Health Promotion Program for Implementation:*



- Evidence-based: supported by rigorous outcome research (preferably RCTs)
- Manualized with training and supervision
- Feasible: Demonstrated track record of successful implementation and likely sustainability

The Spectrum of Integrated Physical Health Care: Integrated Health Promotion

Wellness
Education

General Wellness
Classes

Wellness
Support
Programs

General Wellness
Classes and
Activities (e.g.
walking groups)

Weight Loss,
Fitness, and
Smoking
Cessation

Wellness Coaches,
Weight Management,
Fitness Training,
Smoking Cessation

The Bottom Line

- *Both* obesity and poor fitness are killers
- Changing health behaviors is HARD work but essential to improving health and life expectancy
- The best studies demonstrate modest results in reducing obesity but better results in improving fitness
- What works better? Intensive manualized programs that combine coached physical activity and dietary change lasting at least 6 months (or more)
- Clinically significant weight loss is likely to be achieved by some, but improved fitness by more.....and both are important for heart health

Health Promotion Implementation Resource Guide Checklist: Greater Health Promotion Program Effectiveness

- _____ Designed, evaluated, and proven effective for persons with mental illness
- _____ Proven effective in a randomized trial (RCT)
- _____ *Clinical* significance of outcomes reported
- _____ Participation in physical activity and nutrition (not just education or passive learning)
- _____ Both physical activity and nutrition components
- _____ Trained fitness coach and/or nutritionist
- _____ Self-monitoring and review of goals and outcomes (e.g. weight, activity or exercise, nutrition, etc.)
- _____ Duration of program at least 6 months

Health Promotion Implementation Resource Guide Checklist:

Program Implementation Readiness

- _____ Implemented outside of the original research study
- _____ Implemented in multiple settings/different agencies
- _____ Implemented and provided without grant funding
- _____ Manual designed for providers in real-world settings
(not just a research manual)
- _____ Training and implementation technical assistance
- _____ Fidelity measure
- _____ Core elements defined to allow for local adaptation
- _____ Information on implementation and operation costs

Health Promotion Implementation Resource Guide: Implementation Ready Health Promotion Programs

Practice	Manual Available	Training Available	Contact
RENEW	✓	✓	http://www.cmhsrp.uic.edu/health/weight-wellbeing.asp Catana Brown: cbrown2@midwestern.edu
SIMPLE	✓	✓	www.simpleprogram.org Cenk Tek: cenk.tek@yale.edu.
In SHAPE	✓	✓	Ken Jue: ken@kenjue.com
BT	✓		Rohan Ganguli: Rohan.Ganguli@camh.ca
HEALTH	✓		Christina Mangurian: Christina.Mangurian@ucsf.edu
Lifestyle Intervention	✓	✓	Ren-Rong Wu: wurenrong2005@yahoo.com.cn
DART	✓		Christine McKibbin: cmckibbi@uwyo.edu
Behavioral Wt-loss Intervention	✓		Joseph Gennusa: jgennus1@jhmi.edu
SFW	✓	✓	Betty Vreeland: vreelael@umdnj.edu

Peer-to Peer Wellness Programs

Wellness Recovery Action Planning (WRAP) eight weekly 2.5-hour sessions delivered by peers to enhance hope, personal responsibility, self-advocacy, education, and support

Whole Health Action Management Peer Support Training (WHAM) Peer Support Whole Health and Resiliency (PSWHR) program

Peer Support Whole Health and Resiliency (PSWHR) This overall wellness program closely ties to the Whole Health Action Management (WHAM) program.

Health and Recovery Peer Program (HARP) HARP is based on a chronic disease self-management program in a manualized, six-session intervention, delivered by peer leaders, helps participants become more effective managers of their chronic illness

Breathe Easy, Live Well: based on a modified version of "Learning About Healthy Living **CHOICES** reaches out to smokers with mental illnesses to build their awareness of tobacco use. Peers also provide brief motivational interventions and referrals.

Behavioral Health & Wellness Program (BHWP) a Tobacco Recovery Program and Well Body Program for weight management and nutrition using peers and supervisors to build community awareness, create positive social networks, administer a brief motivational intervention, and run six-sessions educational groups

Future Research Directions?

- Financial incentives
- Use of smartphone and other technology for prompting, monitoring, and support of wellness
- Engaging families and social networks
- Peer led and peer supported interventions
- Ethnically and culturally tailored interventions
- Combined pharmacological and behavioral interventions
- Integrating smoking cessation and substance abuse Rx

What Does it Take to Successfully Implement Integrated Health Promotion Across a State?

Two Federally Funded Initiatives to Support State-wide **Implementation** of In SHAPE in New Hampshire:

- **Statewide Implementation Study:** Training, supervision and technical assistance for organizational change, leadership, and In SHAPE health mentor training
- **CMS Medicaid Wellness Incentive Program:** vouchers for fitness facilities and weight loss programs
rewards for attendance at fitness facilities and smoking cessation

What Does it Take to Successfully Implement Integrated Health Promotion Across the Nation?

- **Currently Under Review at NIH:
National Implementation Study in Collaboration with
the National Council:**
- A comparison of two different approaches to implementation of In SHAPE in 46 mental health organizations across the country:
 - A) Training + Learning Collaborative vs.
 - B) Training + Technical Assistance
- **IF FUNDED: PROJECT TO BEGIN FALL 2013**
- **Free Training, Technical Assistance, and Start-up Funding for In SHAPE for 46 Mental Health Organizations!**



SAMHSA-HRSA Center for Integrated Health Solutions

Questions?

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